Inventors: BINDER, S., & TSENG, S.C.G..



CERTIFICATE OF MAILING BY FIRST CLASS MAIL

pplicants: BINDER, S., & TSENG, S.C.G.

Group: 1651

Application No.:

10/530,164

Examiner:

Filing/371(c) date: April 4, 2005

Docket No.:

TIS-104

For:

RETINAL PIGMENT EPITHELIAL CELL CULTURES ON AMNIOTIC MEMBRANE AND TRANSPLANTATION

DATE OF DEPOSIT: MARCH 16, 2006

I hereby certify that the correspondence attached hereto is being deposited with the United States Postal Service with sufficient postage as First Class Mail on the date indicated above in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Enclosed:

- 1. Return Receipt Postcard (1);
- 2. Certificate of Mailing by First Class Mail (1 page);
- 3. Information Disclosure Statement and Citation (5 pgs.);
- 4. Copy of International Search Report, Notification of Transmittal, and Cover page of WO 2004/033635 A3 (5 pgs); and
- 5. 23 References (251 -total pgs).

Jacqueline M. Arendt, Esq. Registration No. 43,474

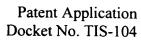
Customer No. 44590

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applic	ant:	Binder, S. & Tseng, S.C.G.	Group Art Unit: 1651			
Applic	ation No.:	10/530,164	Examiner:			
U.S. N	ational Phase o	of PCT/US03/31464				
Filing/	371 (c) Date:	April 4, 2005				
CULT		GMENT EPITHELIAL CELL NIOTIC MEMBRANE AND N	CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail			
Comm P.O. I	RMATION DI nissioner for Pa Box 1450 andria, VA 223		in an envelope addressed to, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on March 16, 2006 Jacqueline M. Arendt			
Sir:	·					
This In	under 37 CFR	closure Statement is submitted: 1.129(a), or sion after Final Rejection)				
[X]] under 37 CFR 1.97(b), or (Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).					
[]	under 37 CFR 1.97(c) together with either:					
	[] a State	ment under 37 CFR 1.97(e), as check	ked below, or			
		.00 fee under 37 CFR 1.17(p), or 07(b) time period, but before final action or notice of all	lowance, whichever occurs first)			
[]	under 37 CFR	1.97(d) together with:				
	[] a Statement under 37 CFR 1.97(e), as checked below, and					
		.00 fee under 37 CFR 1.17(p), or	or before payment of the issue fee)			

[]	under 37 CFR 1.97(i): Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper. (Filed after payment of issue fee)						
Stater	nent Un	der 37 CFR 1.97(e)					
[]	Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or						
[]	No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.						
Stater	nent Un	der 37 CFR 1.704(d) (Patent Term Adjustment) Applies to original applications (other than design) filed on or after May 29, 2000					
[]	comm was no	tem of information contained in the Information Disclosure Statement was cited in a unication from a foreign patent office in a counterpart application and this communication of received by any individual designated in § 1.56(c) more than thirty days prior to the of the Information Disclosure Statement.					
[X]	Enclos	sed herewith is an equivalent of form PTO SB/08a (1449):					
	[X]	Copies of the cited references (numbered 8-31) are enclosed.					
	[]	[] Copies of cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]					
	[X]	The listed Reference 8 (GB 2110531 A) was cited in the enclosed International Search Report.					
	[]	The "concise explanation" requirement (non-English references) for reference under 37 CFR 1.98(a)(3) is satisfied by:					
		[] the explanation provided on the attached sheet.					
		[] the explanation provided in the Specification.					
		[] submission of the enclosed International Search Report.					

	[] submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
	[] the enclosed English language abstract of correspondent application.
[X] I	t is requested that the information disclosed herein be made of record in this application.
[X]	Applicants make no representation that a search has been conducted by Applicants. Applicants also make no representation that the information submitted herewith is in fact material to patentability. The subject application is believed patentable over any of the references.
Metho	od of payment:
[]	A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
r y 1	No fee is due

Respectfully submitted,

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Date: March 14, 2006

OTPE MAR 2 0 2006

MATION DISCLOSURE CITATION

(USE SEVERAL SHEETS IF NECESSARY)

ATTY DOCKET NO. SERIAL NO. TIS-104 10/530,164 APPLICANT(S) SCHEFFER C.G. TSENG, ET. AL.

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FILING DATE/371 (C) DATE:

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			4	APRIL 4, 2005			1651			
		U.S. PATE	ENT DOCUMEN	TS		<u> </u>		-		
*EXAMINER RE	DOCI DAENT NEDADED	DATE		NAME	T	CLASS	er me	1 466	FILING DATE IF	
INITIAL NO.	US 6 152 142	28 Nov. 2000	0 Tseng, SCG			128	898	LASS	APPROPRIATE 20 Feb. 1998	
2.	US 6 226 010 D1	04 Dec. 2001								
			Tseng, SCG & Espana, E. M. Isseroff, R. R. & Schwab, I.R.		na	124	424		25 July 2000	
3.	•				4		378		28 April 200	
4.	US 2002/0039788 A	A1 04 Apr 2002			_ 4	435 ———	366		28 Feb 2001	
5.	US 2003/0208266 A	A1 06 Nov 2003			- 6	523	005		13 Dec 2002	
6.	US 2004/0009590 A	A1 15 Jan 2004			4	135	366		31 Mar 2003	
7.	US 6,045,791	04 Apr 2000	Liu, Y.		4	424			19 May 1995	
		FOREIGN PA	TENT DOCUM	ENTS						
	DOCUMENT NUMBER	DATE	COUNTRY	COUNTRY CLASS SUBCI		LASS			ANSLATION	
8.	GB 2110531 A	22 Jun 1983	U.K.	A61K35	50		NO	YES	ABSTRACT	
-				1	<u> </u>					
<u> </u>	OTHER	DOCUMENTS (Includin	o Author Title I	ate Pertinent Pa	iges Ftc)		_		1	
9.	. <u>,</u>	al Search Report	dated 25-Ja	n-2005, for	PCT/U			1 (3 s	sheets),	
10	Binder, S., et al., "Transplantation of Autologous Retinal Pigment Epithelium in Eyes With Foveal Neovascularization Resulting From Age-Related Macular Degeneration: A Pilot Study, Am J Ophthalmol, 133(2): 215-25 (2002).									
11	Phillips, S.J., et al., "Autologous Transplantation of Retinal Pigment Epithelium After Mechanical Debridement of Bruch's Membrane," Invest Ophthalmol Vis Sci., In Press 1-11 (2002).									
12	Pfeffer, B.A., "Improved Methodology for Cell Culture of Human and Monkey Retinal Pigment Epithelium," <i>Prog. Retin. Eye Res.</i> , Chapter10: 251-91 (1991).									
13		Flood, M.T., et al., "Growth Characteristics and Ultrastructure of Human Retinal Pigment Epithelium in Vitro," <i>Invest Ophthalmol Vis Sci.</i> , 19:1309-20 (1980).								
14		Hu, J., Bok, D., "A cell culture medium that supports the differentiation of human retinal epithelium into functionally polarized monolayers," <i>Molecular Vision</i> , 7:14-19 (2000).								
15	Dutt, K, et al., "Ext	Dutt, K, et al., "Extracellular matrix mediated growth and differentiation in human pigment epithelial cell line 0041," Current Eye Research, 10 (12): 1089-100 (1991).								
16	16. Lu, L., et al., "Retinal pigment epithelium engineering using synthetic biodegradable polymers," <i>Biomaterials</i> , 22: 3345-55 (2001).									

INFORMATION DISCLOSURE CITATION

(USE SEVERAL SHEETS IF NECESSARY)

ATTY DOCKET NO.	SERIAL NO.		
TIS-104	10,530,164		
APPLICANT(S)			
TSENG ET AL			
FILING DATE/371 (C) DATE:	GROUP		
APRIL 4, 2005	1651		

	17.	Kim, J.C., Tseng, S.C.G., "Transplantation of Preserved Human Amniotic Membrane for Surface Reconstruction in Severely Damaged Rabbit Corneas," <i>Cornea</i> , 14:473-84 (1995).
	18.	Tezel, T.H., et al., "Fate of Human Retinal Pigment Epithelial Cells Seeded onto Layers of Human Bruch's Membrane," Invest. Ophthalmol. Vis. Sci., 40:467-76 (1999).
	19.	Dua, H.S., Azuara-Blanco, A., "Amniotic membrane transplantation," <i>Br.J. Ophthalmol</i> , 83:748-52 (1999).
	20.	Grueterich, M., Espana, E., Tseng, S.C.G., "Connexin 43 Expression and Proliferation of Human Limbal Epithelium on Intact and Denuded Amniotic Membrane," <i>Invest Ophthalmol Vis.Sci.</i> , 43:63-71 (2002).
	21.	Meller, D., Tseng, S.C.G., "Conjunctival Epithelial Cell Differentiation on Amniotic Membrane," <i>Invest. Ophthalmol. Vis. Sci.</i> , 40:878-86 (1999).
	22.	Lu, L., et al., "Retinal pigment epithelium cell culture on thin biodegradable poly(DL-lactic-co-glycolic acid) films," J Biomater. Sci. Polymer Edn., 9(11):1187-205 (1998).
	23.	Singh, S., et al., "Natural and artificial substrates for retinal pigment epithelial monolayer transplantation," <i>Biomaterials</i> , 22:3337-343 (2001).
W	24.	DelPriore, L., Tezel, T., "Reattachment Rate of Human Retinal Pigment Epithelium to Layers of Human Bruch's Membrane," <i>Arch Ophthalmol</i> , 116: 335-41 (1998).
-	25.	Koizumi, N., et al., "Cultivation of Corneal Epithelial Cells on Intact and Denuded Human Amniotic Membrane," <i>Invest. Ophthalmol. Vis. Sci.</i> , 41(9):2506-513 (2000 Aug).
	26.	Koizumi, N., et al., "Amniotic Membrane as a Substrate for Cultivating Limbal Corneal Epithelial Cells for Autologous Transplantation in Rabbits," Cornea, 19(1):65-71 (2000).
· ·	27.	Koizumi, N., et al., "An Evaluation of Cultivated Corneal Limbal Epithelial Cells, Using Cell-Suspension Culture," <i>Invest. Ophthalmol. Vis. Sci.</i> , 43 (7): 2114-121 (2002 July).
	28.	Gruetrich, M., Tseng,S.C.G., "Human Limbal Progenitor Cells Expanded on Intact Amniotic Membrane Ex Vivo," Arch Ophthalmol, 120:783-90 (2002 June).
	29.	Espana, E., et al., "Human Keratocytes Cultured on Amniotic Membrane Stroma Preserve Morphology and Express Keratocan," <i>Invest. Ophthalmol. Vis. Sci.</i> , 44(12):5136-141 (2003 December).
	30.	Koh, SW., "VIP Enhances the Differentiation of Retinal Pigment Epithelium in Culture: from cAMP and pp60 ^{c-src} to Melanogenesis and Development of Fluid Transport Capacity," <i>Progress in Retinal and Eye Research</i> , 19(6):669-88 (2000).
	31.	Albert, D.M., et al., "In Vitro Growth of Pure Cultures of Retinal Pigment Epithelium," Arch

EXAMINER	DATE CONSIDERED
EVANDED. Initial hara if reference considered, whether or not citation is in confo	ermance with MPFP 609. Draw line through citation if not in conformance and not